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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,684	10/29/2003	Joseph F. Dellaria	57071US040	5265

32692 7590 10/29/2004

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EXAMINER	
HUANG, EVELYN MEI	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,684	DELLARIA ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,26,31,32 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32* is/are allowed.

6)☒ Claim(s) *22, 26, 31, 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 22, 26, 31, 32, 35 are pending. Claims 1-21, 23-25, 27-30 have been canceled according to the preliminary amendment filed on 10-29-2003. Claims 33, 34 have been canceled according to the amendment filed on 8-6-2004.

Claim Rejections - 35 USC § 112

2. The rejection for Claims 22, 26, 31, 35 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record.

Applicant argues the instant compound induces interferon alpha synthesis, and interferon alpha has been known for decades as an effective anti-neoplastic drug. The nexus between interferon alpha and the treatment of neoplastic diseases is well established as described by Brassard et al. An interferon alpha inducer, imiquimod, has been shown to be effective in treatment of intraeptithelial neoplasia (Davis et al.), basal cell carcinoma (Beurner et al) or squamous cell carcinoma (Hengge et al.).

Brassard, which is published after the filing date of the instant, teaches that interferon alpha administered directly to a patient is effective for treating melanoma. However, Brassard also states that 'the anti-tumor activity of interferon alpha against melanoma seems to be a dose-intensive effect' (Brassard, page 572, column 1, last paragraph) and that interferon alpha 'has demonstrated positive and negative effects on apotosis, highlighting a cell type, state of differentiation and context dependency for the response (page 571, column 2, first paragraph). While imiquimod, an inducer of interferon alpha, has been shown to be effective in the treatment of intraeptithelial neoplasia, basal cell carcinoma or squamous cell carcinoma, in view of the high degree of unpredictability in the pharmaceutical art and the known tissue specificity effect of interferon alpha (Brassard, page 571, column 2, first paragraph), one of ordinary skill in the art would have no basis to extrapolate the use of imiquimod to the treatment of other types of neoplastic diseases, or to extrapolate the results of imiquimod to the inventive compounds which have distinctive structural features than the imiquimod.

Applicant contends that immunotherapy does not depend on disrupting cellular mechanisms within the tumor cells, but instead induce activity of healthy cells of the immune system to eliminate or slow the growth of tumor cells. As a result, immunotherapies such as induction of interferon alpha, have broad spectrum activities having different cellular origins and different mechanisms.

At present, however, there is no known umbrella drug that can treat any type of neoplastic diseases. At the time of the invention, immunotherapy is still at its infancy stage. Except for the use of imiquimod, little is known about the use of an interferon alpha inducing compound to treat neoplastic diseases other than the intraeptithelial neoplasia, basal cell carcinoma or squamous cell carcinoma. More guidance would therefore be required for one of ordinary skill in the art to use all the invention as claimed.

The working examples in the specification are limited to in vitro induction of interferon alpha in human blood cells (pages 96-98 of the specification). No in vivo procedures or dosages are described in the specification. Antitumor activities, in vitro or in vivo, are not found in the specification, without which there is little basis for one of ordinary skill in the art to extrapolate the in vitro interferon-alpha biosynthesis data to the treatment of neoplastic diseases of different origins and sites, especially in view of the high degree of unpredictability in the pharmaceutical art.

Since insufficient teaching and guidance have been provided in the specification, undue experimentation would be required for the skilled in the art to use the inventive compound as claimed.

Double Patenting

3. The timely filed terminal disclaimer has obviated the rejection for Claims 22, 26, 31, 32, 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 17-24, 29-34 of U.S. Patent No. 6664264.

4. The timely filed terminal disclaimer has obviated the rejection for Claims 22, 26, 31, 32, 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 23, 24-27, 33-35, 40-45 of U. S. Patent No. 6667312.

5. The timely filed terminal disclaimer has obviated the provisional rejection for Claims 22, 26, 31, 32, 35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30, 39, 44, 49, 52 of copending Application No. 10/696477.

Conclusion

6. Claim 32 is allowed. See paragraphs 3-5 above.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
Primary Examiner
Art Unit 1625

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